

**K983868 OPMI TWINER SURGICAL MICROSCOPE**Jan 29, 1999  
88 days to decisionK983868 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k983868/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 2, 1998
Decision date	Jan 29, 1999
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Carl Zeiss, Inc.</b>
Location	Mchenry, IL, US
Contact	SCOTT A MARGOLIN
510(k) history	44 submissions · 44 cleared · 1980-2001

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k983868/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 20, 2026